

## About OncoGenerix

OncoGenerix sets the **NEW STANDARD** in injectable process development and manufacturing services.

OncoGenerix offers a fully integrated suite of contract manufacturing services including technical transfer, process development, scale-up, equipment and process validation, formulation, filling, lyophilization, inspection, labeling and packaging, meeting the requirements of the US FDA, EMA, CFDA and PMDA.

The values of OncoGenerix focus on **OPERATOR SAFETY, ENVIRONMENTAL SAFETY, QUALITY and COMPLIANCE**. OncoGenerix utilizes **ADVANCED ASEPTIC MANUFACTURING TECHNOLOGY** and proven methods to provide cost-effective manufacturing services.

OncoGenerix operates within a highly defined, risk-based **QUALITY MANAGEMENT SYSTEM** reflecting the most up-to-date regulatory guidelines for the management of the product life cycle.

## Advantages of OncoGenerix

Flexibility and Scalability:

- OncoGenerix's manufacturing process is fully scalable, allowing clinical production and commercial production in the same process. We can accommodate a batch range from 1 to 1,000 liters, with a vial range of 2mL to 100mL.

Communication and Customer Focus:

- To ensure compliance, all site documents are in Chinese and English with English being the primary language of the site.
- OncoGenerix provides an empowered dedicated project manager to coordinate all activities on behalf of the client on site. Our services are focused on individual client's requirements and goals.

Commitment to Safety and the Environment:

- Comprehensive site environmental, health and safety systems.
- Integrated liquid waste management and treatment system allows site-based treatment and neutralization or removal using certified waste management contractors.
- Defined biohazard and solid waste managements systems using certified waste management contractors.

Fully Integrated Process Development, Validation and Commercialization Services:

- Detailed evaluation of innovator product development status and preparation of strategy for process development, process validation, stability, regulatory filing and commercialization.
- Preparation of efficient and effective technical transfer and scale up plans from product clinical development through commercial manufacturing, considering the total product life cycle.
- Product process development and validation, including analytical methods, formulation, product fluid path (single use and dedicated), lyophilization cycle, container closure integrity, product inspection, product packaging and cleaning.

#### State of the Art Manufacturing Capabilities:

- Using ISO 5 isolator based advanced aseptic manufacturing technology located in an ISO 7 cleanroom environment, ensuring high levels of sterility and containment.
- Meeting US FDA, EMA, CFDA & PMDA regulatory requirements for clinical and commercial supplies.
- Using a QbD risk-based approach (FDA Process Validation 2011, ICH Q8, ICH Q9, ICH q10, GAMP, ISPE Commissioning Qualification Baseline, 21 CFR 211 and EU GMP regulations) within a Defined Life Cycle (ASTM E2500) for implementation, qualification validation of process and facilities. This approach uses the highest quality and compliance standards resulting in products that fully meet the clinical needs of the patient.

#### Cost Effectiveness:

- OncoGenerix drives cost effectiveness through the quality management system where continuous evaluation and improvement is used to ensure a high level of equipment and process reliability and availability.
- OncoGenerix's engineering and maintenance teams have subject matter experts for the facility control systems, and each item of process equipment. This allows diagnostic and repair of issues in-house without the need for external vendor support.
- OncoGenerix uses a high level of automation, minimizing the potential of operator intervention errors.
- OncoGenerix uses waste heat and water recovery systems to minimize utility consumption.

#### Open Information Sharing (Open Source):

- As a part of our commitment to our clients, OncoGenerix provides the client total access to their specific product and process technology information including procedures, protocols and data gained through realization of the product manufacturing process.
- We also provide our clients with client office facilities for on-site monitoring of the manufacturing process.

#### World Class Engineering Services:

- OncoGenerix has a world-class engineering team with the capability to develop, implement and qualify custom manufacturing technology from a single item of equipment to an entire facility.
- The OncoGenerix engineering team provides the client with the ability to test a manufacturing technology off-line from their facility and transfer the technology to their

facility once established.

- The OncoGenerix site team is self-sufficient and has all the necessary skills to undertake equipment design, testing (including test method development, note book studies and engineering studies) qualification, maintenance and repair, eliminating reliance on outside equipment vendors.

## Our Leadership



**Dmitry Itkin**

### *Dmitry Itkin*

With 25+ years of experience, Dmitry has managed the startup and guided to profitability many enterprises across a range of industries. He started an API manufacturing company for anthracyclines that became the world leader for high-quality doxorubicin, epirubicin, idarubicin and several other important APIs. Under his leadership these anthracyclines were approved by US FDA. His next focus was on implementing a marketing strategy to supply these APIs to more than 25 countries and territories. Dmitry's specialty areas are strategic planning, project funding, financial management, international marketing, regulatory compliance, product patent management and approvals in Europe, United States and Asia. Dmitry is one of the founders and the leading strategist behind OncoGenerix USA, Inc. Dmitry's current focus is to have OncoGenerix USA provide high quality, cost effective manufacturing services for injectable oncology products from clinical to commercial supplies.



**Dr. Roland Franke**

*Chief Scientific Officer and V.P. of Business Development*

With 20+ years in the pharmaceutical industry, Dr. Franke has diverse experience in research and development, pharmaceutical mergers and acquisitions, business startup, and operation. In 1999, Dr. Franke was a Co-Founder & CEO of a company focused on developing and manufacturing bulk active taxanes through novel semi-synthetic production technology, which was acquired by Phyton Biotech in 2009. As VP of Business Development and Chief Technical Officer of Phyton Biotech, Dr. Franke extended the customer base for docetaxel and paclitaxel APIs beyond North America and Europe to major markets in Asia delivering an average revenue growth of approximately 40% per year. Under his technical leadership, Phyton developed and implemented the world's largest production scale for paclitaxel API from plant cell fermentation. For that work, Phyton's R&D Group received the Research Group of the Year Award in the International Life Science competition in 2011. Dr. Franke has authored numerous patents in the field of taxanes and has 22 publications. Dr. Franke holds a Bachelor of Science from University of Freiburg, a Master of Science from University of Freiburg, a Ph.D. in Biochemistry from Massachusetts Institute of Technology and a Master of Science and MBA from the Sloan School of Management, Massachusetts Institute of Technology.



**Sabrina Zhu**

*Business Development in Asian Markets*

Sabrina has extensive experience in market analysis, market strategy preparation and customer network establishment. She shows insight in developing product market opportunities / breakthrough pathways and is familiar with registration requirements for multiple markets. Sabrina is specialized in developing emerging markets in South-East Asia, and the regulated markets of Japan, and China. She has engaged in several partnership negotiations and license-in project evaluations. Sabrina holds a Bachelor's degree in Pharmaceutical Engineering from China Pharmaceutical University.

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## **COMPLIANCE**

[Global Compliance](#)

Quality Management System  
Facility Implementation Strategy

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